Coverage of Routine Costs of Qualifying Clinical Trials

Proposed by Cori Cook of EBMS
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(1) A health benefit policy, subject to Title 33 of the Montana Code, shall provide coverage for the routine costs of the care of patients enrolled in and participating in qualifying clinical trials.

(2) As used in subsection (1) of this section, "routine costs":

(a) Means medically necessary conventional care, items or services covered by the health benefit policy if typically provided absent a clinical trial.

(b) Does not include:

(A) The drug, device or service being tested in the clinical trial unless the drug, device or service would be covered for the indication by the health benefit policy if provided outside of a clinical trial;

(B) Items or services required solely for the provision of the drug device or service being tested in the clinical trial;

(C) Items or services required solely for the clinically appropriate monitoring of the drug, device, or service being tested in e clinical trial;

(D) Items or services required solely for the prevention, diagnosis, or treatment of complications arising from the provision of the drug, device or service being tested in the clinical trial;

(E) Items or services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;

(F) Items or services customarily provided by a clinical trial sponsor;

(G) Items or services that are not covered by the health policy if provided outside the clinical trial; or

(H) The cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) As used in subsection (1) of this section, "qualifying clinical trial" means a phase II, III, or IV clinical trial that is:

(a) Funded by the NIH, CDC, AHRQ, CMS, DOD, or the VA;

(b) Supported by a center or cooperative group that is funded by NIH, CDC, AHRQ, CMS, DOD or the VA;

(c) Approved and subject to oversight by an Institutional Review Board (IRB) and governed by a written protocol guided by safety, toxicity and/or efficacy standards in comparisons to conventional alternatives;

(d) Conducted as an investigational new drug application, an investigational device exemption or a biologics license application subject to approval by the FDA; or

(e) Exempt by federal law from the requirement to submit an investigational new drug application to the FDA.

(4) The coverage required by this section may be subject to other provisions of the health benefit policy that apply to other benefits, including but not limited to copayments, deductibles, and coinsurance.

(5) An insurer that provides coverage required by this section is not, based upon that coverage, liable for any adverse effects of the clinical trial.

(6) The health benefit policy and the patient have the right to request and receive a copy of the informed consent the patient executes for participation in the clinical trial and they also have the right to request and receive a copy of the qualified clinical trial's protocol before determining if any benefits are payable.

(7) Any deviation from the approved protocol will render the entire treatment and related care ineligible for coverage.